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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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08/978,634

11/25/1997

ELAZAR RABBANI

ENZ-53(DIV-2

4640

28171

7590

07/09/2010

ENZO BIOCHEM, INC.

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NEW YORK, NY 10022

EXAMINER

SHIN, DANA H

ART UNIT

PAPER NUMBER

1635

MAIL DATE

DELIVERY MODE

07/09/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 08/978,634	<b>Applicant(s)</b> RABBANI ET AL.	
	<b>Examiner</b> DANA SHIN	<b>Art Unit</b> 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 275,289,290 and 296-301 is/are pending in the application.
- 4a) Of the above claim(s) 289,290 and 298-301 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 275,296 and 297 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3-29-2010</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 29, 2010 has been entered.

### ***Status of Claims***

Claims 275, 289-290, and 296-301 are pending in the instant application. Claims 289-290 and 298-301 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on March 2, 2008. Accordingly, claims 275 and 296-297 are under examination on the merits in the instant case.

### ***Response to Arguments***

Applicant's arguments, see pages 5-15 of the remarks, filed on March 29, 2010, with respect to the rejection(s) of claim(s) 275 and 296-297 under 35 U.S.C. 102(b), 35 U.S.C. 102(e), and 35 U.S.C. 103(a) have been fully considered and are persuasive. Therefore, the rejections

Art Unit: 1635

have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the claim amendments and newly found prior art references. See below.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 275 and 296 are rejected under 35 U.S.C. 102(e) as being anticipated by Cantor et al. (US 5,561,043).

Cantor et al. teach a self-assembling multimeric nucleic acid construct comprising two single-stranded nucleic acids that are complementary and hybridize with each other, thereby forming a double-stranded portion “when, for example, a particular structure is desired of the assembled network of constructs or to facilitate coupling of one or more functional groups.”, wherein the functional groups include cytokines, proteins, erythropoietin, interleukins, and hormones, wherein the functional groups are attached to one or more nucleic acids and that “Multiple functional groups can be attached to a single construct and, if desired, constructs can be entirely saturated.” See column 6, lines 8-12, 30-65. Accordingly, all claim limitations are taught by Cantor et al.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 275 and 296-297 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cantor et al. (US 5,561,043) in view of Osborne et al. (*PNAS*, 1976, 73:4536-4540, citation of record).

Cantor et al. teach a self-assembling multimeric nucleic acid construct comprising two single-stranded nucleic acids that are complementary and hybridize with each other, thereby forming a double-stranded portion “when, for example, a particular structure is desired of the assembled network of constructs or to facilitate coupling of one or more functional groups.”, wherein the functional groups include cytokines, proteins, erythropoietin, interleukins, and hormones, wherein the functional groups are attached to one or more nucleic acids and that “Multiple functional groups can be attached to a single construct and, if desired, constructs can

Art Unit: 1635

be entirely saturated.” See column 6, lines 8-12, 30-65. Cantor et al. do not explicitly teach the hormones include insulin.

Osborne et al. teach that insulin is a hormone and is a ligand that binds to its receptor, insulin receptor. See the entire reference.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a self-assembling multimeric nucleic acid construct comprising multiple units of insulin.

One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success because a self-assembling multimeric construct comprising two complementary strands of nucleic acids, further comprising multiple functional groups such as hormones was a known construct as taught by Cantor et al., and because insulin is a species of hormones as taught by Osborne et al. Accordingly, the claims taken as a whole would have been *prima facie* obvious at the time of filing.

Claims 275 and 296-297 are rejected under 35 U.S.C. 103(a) as being unpatentable over Priest (US 5,391,723, applicant's citation) in view of Osborne et al. (*PNAS*, 1976, 73:4536-4540, citation of record).

Priest teaches an isolated composition structure having a single-stranded oligonucleotide, a linker, and a protein, wherein the protein is bound, preferably covalently, to the linker, wherein the linker is bifunctional such that it binds to both the protein and the single-stranded oligonucleotide, wherein the protein binds to its receptor at the target cell, thereby suggesting that the protein is a cell surface receptor ligand, wherein the linker is “a nucleotide, a nucleotide

Art Unit: 1635

derivative or a precursor thereof.” such that the linker binds (or links) the single-stranded oligonucleotide to the protein, wherein the linker covalently binds to the protein. See column 3, lines 46-52. Priest also teaches that the single-stranded oligonucleotide can bind to a complementary or partially complementary oligonucleotide strand to form a duplex region through hydrogen binding. See column 2, lines 15-18, lines 31-41; column 3, lines 17-49. Priest does not teach the protein is insulin, nor do they teach a multimeric composition.

Osborne et al. teach that insulin is a ligand that binds to its receptor, insulin receptor. See the entire reference.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a composition comprising multiple units of insulin attached to multiple units of oligonucleotide linkers, which are hybridized to a complementary single-stranded polynucleotide.

One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success because a monomer structure comprising a single-stranded oligonucleotide, an oligonucleotide-based linker, and a ligand protein was known in the art as taught by Priest, and because insulin is an art-recognized ligand as taught by Osborne et al. Since making a composite composition comprising more than one such monomer structure is a logical option for various purposes (e.g., multimerization of insulin for experimental purposes), one of ordinary skill in the art would have been motivated to make a combination product comprising multiple, identical monomeric units of insulin, wherein each monomeric unit of insulin is covalently bound to a single-stranded oligonucleotide linker, which in turn is hybridized to a single-stranded oligonucleotide. See *In re Kerkhoven* 626 F.2d 846, 850, 205 USPQ 1069, 1072

Art Unit: 1635

(CCPA 1980), wherein the court expressed the following: “It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose...[T]he idea of combining them flows logically from their having been individually taught in the prior art.”

Accordingly, the claimed invention taken as a whole would have been *prima facie* obvious at the time of filing.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting



Art Unit: 1635

ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 275 and 296-297 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 246 and 264-265 of copending Application No. 08/978,632. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims and the reference claims are drawn to a multimeric nucleic acid construct comprising a ligand. Although the reference claims do not explicitly recite the words “multimeric” and “insulin” claimed in the instant claims, the specification of 08/978,632 teaches that the claimed nucleic acid construct reads on a multimeric complex composition comprising insulin molecules. See paragraphs 0044-0045, and 0223. Hence, the scope of the instant claims is encompassed by that of the reference claims, and therefore the claims are not patentably distinct from each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

No claim is allowed.

Art Unit: 1635

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANA SHIN whose telephone number is (571)272-8008. The examiner can normally be reached on Monday through Friday, 7am-3:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydoun Sajjadi (Acting SPE) can be reached on 571-272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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